



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-6730]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Reporting

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0437. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

This information collection supports FDA regulations and FDA's Medical Device Reporting program. Section 519(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i(a), (b), and (c)) requires user facilities, manufacturers, importers, and distributors of medical devices to report adverse events involving medical devices to FDA. These provisions are codified in part 803 (21 CFR part 803), Medical Device Reporting. As amended most recently by the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52), medical device manufacturers and importers must submit medical device reports (MDRs) using FDA's electronic submission system. User facilities, however, may elect to submit reports using paper-based Form FDA 3500A--MedWatch--Mandatory Reporting (approved under OMB control number 0910-0291). The regulations also establish recordkeeping requirements and provide for certain exemptions, variances, or alternative forms of reporting. Exemptions and/or variances from individual reporting must be requested in writing and must receive Agency approval. Additionally, the regulations permit user facilities to submit paper-based annual reports, for which we have developed Form FDA 3419 entitled "Medical Device Reporting Annual User Facility Report."

This information collection also includes the use of existing formats such as Form FDA 3500A<sup>1</sup>--MedWatch--Mandatory Reporting to allow manufacturers to summarize in a single report multiple events with shared characteristics for device associated reportable malfunction events. For example, the Voluntary Malfunction Summary Reporting Program (VMSRP)<sup>2</sup> provides recommendations for manufacturers of certain devices to submit a single report that summarizes multiple device associated reportable malfunction events on a quarterly basis. The VMSRP was established under section 519(a)(1)(B)(ii) of the FD&C Act and reflects goals for streamlining malfunction reporting as outlined in the Medical Device User Fee Amendments

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<sup>1</sup> Form FDA 3500A is approved under OMB control number 0910-0291.

<sup>2</sup> In the *Federal Register* of August 17, 2018 (83 FR 40973), FDA issued a notification permitting manufacturers to report certain device malfunction MDRs in summary form on a quarterly basis.

(MDUFA) IV “Commitment Letter” for 2018 through 2022 agreed to by FDA and industry and submitted to Congress. The Commitment Letter was finalized with the passage of FDARA on August 18, 2017, and, as passed, is entitled “MDUFA Performance Goals And Procedures, Fiscal Years 2018 Through 2022.”<sup>3</sup>

The information that is obtained from this information collection will be used to evaluate risks associated with medical devices and enable FDA to take appropriate measures to protect the public health. Complete, accurate, and timely adverse event information is necessary for the identification of emerging device problems so the Agency can protect the public health under section 519 of the FD&C Act. FDA makes the releasable information available to the public for downloading on its website. Respondents are manufacturers and importers of medical devices and device user facilities.<sup>4</sup>

In the *Federal Register* of April 29, 2021 (86 FR 22671), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. Upon our own review, however, we have updated submission figures from our VMSRP program and supplemental reports under § 803.56 (21 CFR 803.56) to reflect an increase in submissions. Since publication of our 60-day notice, therefore, we have modified our estimated burden for collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity/21 CFR Section	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours <sup>2</sup>
Exemptions/Variations--803.19		6	135.8	815	0.10 (6 minutes)	82
User Facility Reporting--803.30 and 803.32		271	17.2	4,661	0.35 (21 minutes)	1,631
User Facility Annual Reporting--803.33	3419	93	2	186	1	186
Importer Reporting, Death and Serious Injury--803.40 and 803.42		112	440.25	49,308	0.10 (6 minutes)	4,931
Manufacturer Reporting--803.50, 803.52 and 803.53		1,799	809.83	1,456,884	0.10 (6 minutes)	145,688

<sup>3</sup> Available at: <https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf>.

<sup>4</sup> Device user facility means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in § 803.3 (21 CFR 803.3), which is not a physician’s office (also defined in § 803.3).

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity/21 CFR Section	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours <sup>2</sup>
Voluntary Malfunction Summary Reporting Program		67	695.15	46,575	0.10 (6 minutes)	4,658
Supplemental Reports--803.56		1,291	438	565,458	0.10 (6 minutes)	56,546
Total						213,722

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Number has been rounded.

The number of respondents to the information collection is based on MDRs received by FDA recently. The annual frequency per response and total annual responses shown are based on the number of MDRs reported during the same period. Based on the scope and conditions of the VMSRP and our experience with MDR reporting, FDA estimates that approximately 10 percent of malfunction reports would continue to be submitted as individual reports. Approximately 62 percent of the manufacturer reports received under §§ 803.50, 803.52 and 803.53 are malfunction reports (903,268 of the 1,456,884 total annual responses received in 2020).

*Supplemental Reports--§ 803.56.* We have increased our estimate, of the number of supplemental reports to reflect a corresponding increase of annual submissions, as reflected in table 1, row 7.

*Voluntary Malfunction Summary Reporting Program.* The VMSRP includes the same respondent pool as individual manufacturer reporting. Based on a current review of Agency data, we have increased our estimate to reflect an increase in annual submissions, as reflected in table 1, row 6.

Table 2.--Estimated Annual Recordkeeping Burden<sup>1</sup>

Activity/21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
MDR Procedures--803.17	1,799	1	1,799	3.3	5,937
MDR Files--803.18	1,799	1	1,799	1.5	2,699
Total					8,636

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents in table 2 is based on the MDRs reported to FDA's internal databases recently. We believe that the majority of respondents (manufacturers, user facilities,

and importers) have already established written procedures and MDR files to document complaints and information to meet the MDR requirements as part of their internal quality control system.

Table 3.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

Activity/21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours <sup>2</sup>
Importer Reporting, Death and Serious Injury-803.40 and 803.42	112	25	2,800	0.35 (21 minutes)	980

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Number has been rounded.

The number of respondents for each CFR section in table 3 was identified from the MDRs reported to FDA's internal databases during the period recently.

Since the publication of the 60 day notice we have adjusted our burden estimate. Our estimated burden for the information collection reflects an increase of 155,360 total burden hours and a corresponding increase of 1,566,458 total annual responses. This increase corresponds with data obtained from our database.

Dated: July 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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